We claim:

1. A dissolution-controlled chemical delivery device providing substantially constant controlled-release of at least one active ingredient into a fluid medium throughout a substantial portion of the delivery period which composition comprises:

   (*i*) a shaped core (*a*) having at least one planar release face wherein the dimensions of said face remain constant throughout a substantial portion of the delivery period, (*b*) comprising a compressed mixture of the active ingredient homogeneously mixed with at least one dissolution regulator operable to release the active ingredient from said release face, and optionally (c) having a score circumscribed on the surface to secure the coating;

   (*ii*) a coating surrounding and adhering to said core except the release face(s), said coating containing an insoluble polymer and pore-forming elements operable to create channels in said insoluble coating to permit disintegration of the coating after release of said active ingredient is completed.

2. A device according to claim 1 wherein said device is rectangular and said planar release surface is a square.

3. A device according to claim 1 wherein said core is a cylinder and said planar release face is a circle.

4. A device according to claim 1 wherein said core is a prism and said planar release surface is a polygon

5. A device according to claim 1 wherein said core has two exposed planar release surfaces.

6. A device according to claim 1 wherein the polymer coating is selected from a group consisting of ethyl cellulose, cellulose acetate, cellulose acetate butyrate and cellulose acetate phthalate, polyvinyl alcohol, polyvinyl acetate and methacrylic acid copolymers.

7. A device according to claim 1 wherein said pore-forming element(s) is selected form a group consisting of dextrose, fructose, glucose, dextrates, sorbitol, propylene glycol, glycerin and carbowax.

8. A device according to claim 1 wherein said dissolution regulator is selected from a group consisting of hydroxypropyl cellulose, hydroxyethyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, methyl cellulose, soluble modified starches, gelatin, and acacia.

9. A device according to claim 1 where said active ingredient is a pharmaceutical agent for human use.

10. A device according to claim 9 where said active ingredient is selected from a group consisting of psychotherapeutic agents, anti-diabetic drugs, anticonvulsants, cardiovascular drugs, stroke treatment agents, respiratory therapies, anti-infective agents, migraine therapies, urinary tract agents, contraceptives, analgesics, cholesterol reducers, anti-arthritic agents, gastrointestinal products, muscle-relaxants, muscle-contractants, anti-Parkinson agents, anti-inflammatory agents, hormonal agents, diuretics, electrolytes, serotonin agonists and antagonists H2-antagonists muscle relaxants.

11. A device according to claim 9 where said active ingredient is selected from a group consisting of aspirin, bupropion hydrochloride, buspirone hydrochloride, carbamazepine, carbidopa, cephalosporin, cimetidine hydrochloride, citalopram hydrobromide, clarithromycin, clonidine, diclofenac sodium, diltiazem hydrochloride, dipyridamole, divalproex sodium, doxazosin mesylate, enalapril maleate, ethinyl estradiol, etodolac, fexofenadine hydrochloride, glipizide, haloperidol, ibuprofen, indomethacin, isosorbide dinitrate, isradipine, ketoprofen, labetalol, lansoprazole, levodopa, lithium carbonate, loratidine, lovastatin, methascopolomine chloride, metformin hydrochloride, metronidazole, methylphenidate hydrochloride, metoprolol succinate, morphine sulfate, naproxen sodium, nifedipine, nisoldipine, norethindrone acetate, omeprazole, oxybutynin chloride, oxycodone hydrochloride, penicillin, pentoxifylline, potassium chloride, pseudoephedrine hydrochloride, rabeprazole sodium, ranitidine hydrochloride,

salbutamol, terfenadine, theophylline, tramadol hydrochloride, trandolapril, venlafaxine hydrochloride, verapamil hydrochloride, and alternative or pharmaceutically acceptable salts thereof. .

12. A device according to claim 1 where said active ingredient is a pharmaceutical agent for veterinary use.

13. A device according to claim 1 where said active ingredient is an insecticide or fungicide.

14. A device according to claim 1 where said active ingredient is a biocide or disinfectant.

15. A process for the preparation of a chemical delivery device according to claim 1 by dry granulation process comprising the steps of:

(a) blending said active ingredient and a dissolution regulator and optionally with a diluent;

(b) optionally milling and sieving the resulting blend with a mesh size suitable for the specific application;

(c) mixing said blend with a soluble or insoluble lubricant and compressing said blend into tablet with an appropriate shape in a punch machine;

(d) coating said tablet with a mixture of an insoluble polymer and pore-forming elements using a compression-coating machine.

16. A process according to claim 15 wherein said diluent is selected from the group consisting of lactose, sucrose, carbowax, dextrates, glucose, fructose, sorbitol, mannitol, calcium sulfate, dicalcium phosphate, microcrystalline cellulose and starch.

17. A process according to claim 15 wherein said lubricant is selected from the group consisting of stearic acid, sodium stearate, calcium stearate and sodium lauryl sulfate.

18. A process for the preparation of a chemical delivery device according to claim 1 by wet granulation process comprising:

(a) blending said biologically active ingredient and a dissolution regulator with water, an organic solvent or a mixture of water and an organic solvent and optionally with a diluent;

(b) drying the resulting blend at an appropriate temperature, milling and sieving the resulting blend with a mesh size suitable for the specific application;

(c) mixing said blend with a soluble or insoluble lubricant and compressing the blend into tablet into an appropriate shape in a punch machine;

(d) coating said tablet with a mixture of an insoluble polymer and pore-forming elements using a compression-coating machine.

19. A process according to claim 18 wherein said diluent is selected from the group consisting of lactose, sucrose, carbowax, dextrates, glucose, fructose, sorbitol, mannitol, calcium sulfate, dicalcium phosphate, microcrystalline cellulose and starch.

20. A process according to claim 18 wherein said lubricant is selected from the group consisting of stearic acid, sodium stearate, calcium stearate and sodium lauryl sulfate.

21. A method of delivering a substantially constant controlled release of an active compound into a fluid medium comprising:

(a.) incorporating at least one biologically active ingredient into a tablet having:

(*i*) a shaped core (*a*) having at least one planar release face wherein the dimensions of said face remain constant throughout a substantial portion of the delivery period, and (*b*) comprising a compressed mixture of the biologically active ingredient homogeneously mixed with at least one dissolution regulator operable to release the biologically active ingredient from said release face, and optionally (c) having a score circumscribed on the surface to secure the coating;

(*ii*) a coating surrounding and adhering to said core except the release face(s), said coating containing mixture of an insoluble polymer and pore-forming elements operable to create channels in said coating to permit disintegration of the coating after release of said active ingredient is completed said coating disintegrating over a substantially longer period of time than is required for said dissolution regulator to release said biologically active ingredient; and,

(b) placing said tablet in a fluid medium in need of the presence of said active ingredient.

22. A dissolution-controlled chemical delivery device providing controlled variable release of at least one biologically active ingredient into a fluid medium throughout a substantial portion of the delivery period which composition comprises

(*i*) a shaped core (*a*) having at least one planar release face wherein the dissolution of said face causes at least one of the dimensions of said face to vary thereby increasing or decreasing the surface area of said face throughout a substantial portion of the delivery period, and (*b*) containing the biologically active ingredient homogeneously mixed with at least one dissolution regulator operable to release the biologically active ingredient from said release face, and;

(*ii*) a coating surrounding and adhering to said core except the release face(s), said coating containing an insoluble polymer or a mixture of an insoluble polymer and pore-forming elements operable to create channels in said impermeable coating to permit disintegration of the coating after release of said active ingredient is completed.

23. A device according to claim 22 wherein said core is a truncated bipyramid as depicted in Figure 5 and said planar release face is a square.

24. A device according to claim 22 wherein said device is two frustums of a cone said frustums being attached at either base as depicted in Figure 3 and 4 wherein said planar release surface is a circle.

25. A device according to claim 22 wherein said polymer coating is selected from a group consisting of ethyl cellulose, cellulose acetate, cellulose acetate butyrate and cellulose acetate phthalate, polyvinyl alcohol, polyvinyl acetate and methacrylic acid copolymers.

26. A device according to claim 22 wherein said pore-forming element is selected form a group consisting of dextrose, fructose, glucose, dextrates, sorbitol and carbowax.

27. A device according to claim 22 wherein said dissolution regulator is selected from a group consisting of hydroxypropyl cellulose, hydroxyethyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, methyl cellulose, soluble modified starches, gelatin, and acacia;

28. A device according to claim 22 where the active ingredient is a pharmaceutical agent for human use.

29. A device according to claim 28 where the active ingredient is selected from a group consisting of psychotherapeutic agents, antidiabetic drugs, anticonvulsants, cardiovascular drugs, stroke treatment agents, respiratory therapies, anti-infective agents, migraine therapies, urinary tract agents, contraceptives, analgesics, cholesterol reducers, antiarthritic agents, gastrointestinal products, muscle-relaxants, muscle-contractants, anti-Parkinson agents, anti-inflammatory agents, hormonal agents, diuretics, electrolytes, serotonin agonists and antagonists H2-antagonists muscle relaxants.

30. A device according to claim 28 where the active ingredient is selected based a suitable half-life and adsorption characteristics from a group consisting of aspirin, bupropion hydrochloride, buspirone hydrochloride, carbamazepine, carbidopa, cephalosporin, cimetidine hydrochloride, citalopram hydrobromide, clarithromycin, clonidine, diclofenac sodium, diltiazem hydrochloride,

dipyridamole, divalproex sodium, doxazosin mesylate, enalapril maleate, ethinyl estradiol, etodolac, fexofenadine hydrochloride, glipizide, haloperidol, ibuprofen, indomethacine, isosorbide dinitrate, isradipine, ketoprofen, labetalol, lansoprazole, levodopa, lithium carbonate, loratidine, lovastatin, methascopolomine chloride, metformin hydrochloride, metronidazole, methylphenidate hydrochloride, metoprolol succinate, morphine sulfate, naproxen sodium, nifedipine, nisoldipine, norethindrone acetate, omeprazole, oxybutynin chloride, oxycodone hydrochloride, penicillin, pentoxifylline, potassium chloride, pseudoephedrine hydrochloride, rabeprazole sodium, ranitidine hydrochloride, salbutamol, terfenadine, theophylline, tramadol hydrochloride, trandolapril, venlafaxine hydrochloride, verapamil hydrochloride, and alternative or pharmaceutically acceptable salts thereof.

31. A device according to claim 22 where said active ingredient is a pharmaceutical agent for veterinary use.

32. A device according to claim 22 where said active ingredient is an insecticide or fungicide.

33. A device according to claim 22 where said active ingredient is a biocide or disinfectant.

34. A process for the preparation of a chemical delivery device according to claim 22 by dry granulation process comprising the steps of:

(a) blending said active ingredient and a dissolution regulator and optionally with a diluent;

(b) optionally milling and sieving the resulting blend with a mesh size suitable for the specific application;

(c) mixing said blend with a soluble or insoluble lubricant and compressing said blend into tablet with an appropriate shape in a punch machine;

(d) coating said tablet with a coating containing an insoluble polymer or a mixture of an insoluble polymer and pore-forming elements using a compression-coating machine.

35. A process for the preparation of a chemical delivery device according to claim 22 by wet granulation process comprising:

(a) blending said biologically active ingredient and a dissolution regulator with water, an organic solvent or a mixture of water and an organic solvent and optionally with a diluent;

(b) drying the resulting blend at an appropriate temperature, milling and sieving the resulting blend with a mesh size suitable for the specific application;

(c) mixing said blend with a soluble or insoluble lubricant and compressing the blend into tablet into an appropriate shape in a punch machine;

(d) coating said tablet with a mixture containing an insoluble polymer or a mixture of an insoluble polymer and pore-forming elements using a compression-coating machine.

36. A method of delivering an active ingredient with a controlled variable release of an active compound into a fluid medium comprising:

(a.) incorporating at least one biologically active ingredient into a tablet having:

(*i*) a shaped core (*a*) having at least one planar release face wherein the dissolution of said face causes at least one of the dimensions of said face to vary thereby increasing or decreasing the surface area of said face throughout a substantial portion of the delivery period, and (*b*) containing a compressed mixture of the biologically active ingredient homogeneously mixed with at least one dissolution regulator operable to release the biologically active ingredient from said release face; and,

(*ii*) a coating surrounding and adhering to said core except the release face(s), said coating containing an insoluble polymer or a mixture of an insoluble polymer and pore-forming elements

operable to create channels in said impermeable coating to permit disintegration of the coating after release of said active ingredient is completed said coating disintegrating over a substantially longer period of time than is required for said dissolution regulator to release said biologically active ingredient; and,

(b) placing said tablet in a fluid medium in need of the presence of said active ingredient.

37. A diffusion-controlled chemical delivery device providing substantially constant-controlled-release of at least one active ingredient into a fluid medium throughout a substantial portion of the delivery period which composition comprises:

(*i*) a shaped core having (*a*) at least one planar release face wherein the dimensions of said face remain constant throughout a substantial portion of the delivery period, and (*b*) a planar dissolution surface within the matrix wherein the surface area of said dissolution surface increases throughout the delivery period to compensate for an increase in the diffusion path length, and, containing (c) a compressed mixture of the active ingredient homogeneously mixed with at least one compound insoluble in the fluid media operable to release the active ingredient from said release surface; and,

(*ii*) a coating surrounding and adhering to said core except the release face(s), said coating containing an insoluble polymer or a mixture of an insoluble polymer and pore-forming elements operable to create channels in said impermeable coating to permit disintegration of the coating after release of said active ingredient is completed.

38. A device according to claim 37 herein said core is a truncated bipyramid as depicted in Figure 5 and said planar release face is a square.

39. A device according to claim 37 wherein said device is <u>two frustums of a cone</u> said frustums being attached at either base <u>as depicted in Figure 3</u> wherein said planar release surface is a circle.

40. A device according to claim 37 wherein said polymer coating is selected from a group consisting of ethyl cellulose, cellulose acetate, cellulose acetate butyrate and cellulose acetate phthalate, polyvinyl alcohol, polyvinyl acetate and methacrylic acid copolymers.

41. A device according to claim 36 wherein said pore-forming element is selected form a group consisting of dextrose, fructose, glucose, dextrates, sorbitol and carbowax.

42. A device according to claim 36 wherein said insoluble component of the core is selected from a group consisting of ethyl cellulose, cellulose acetate, cellulose acetate butyrate and cellulose acetate phthalate, polyvinyl alcohol, polyvinyl acetate and methacrylic acid copolymers.

43. A device according to claim 36 where said active ingredient is a pharmaceutical agent for human use.

44. A device according to claim 36 where said active ingredient is selected from a group consisting of psychotherapeutic agents, anti-diabetic drugs, anticonvulsants, cardiovascular drugs, stroke treatment agents, respiratory therapies, anti-infective agents, migraine therapies, urinary tract agents, contraceptives, analgesics, cholesterol reducers, anti-arthritic agents, gastrointestinal products, muscle-relaxants, muscle-contractants, anti-Parkinson agents, anti-inflammatory agents, hormonal agents, diuretics, electrolytes, serotonin agonists and antagonists H2-antagonists muscle relaxants.

45. A device according to claim 36 where the pharmaceutical active is selected from a group consisting of aspirin, bupropion hydrochloride, buspirone hydrochloride, carbamazepine, carbidopa, cephalosporin, cimetidine hydrochloride, citalopram hydrobromide, clarithromycin, clonidine, diclofenac sodium, diltiazem hydrochloride, dipyridamole, divalproex sodium, doxazosin mesylate, enalapril maleate, ethinyl estradiol, etodolac, fexofenadine hydrochloride, glipizide, haloperidol, ibuprofen, indomethacine, isosorbide dinitrate, isradipine, ketoprofen, labetalol, lansoprazole, levodopa, lithium carbonate, loratidine, lovastatin, methascopolomine chloride, metformin hydrochloride, metronidazole,

methylphenidate hydrochloride, metoprolol succinate, morphine sulfate, naproxen sodium, nifedipine, nisoldipine, norethindrone acetate, omeprazole, oxybutynin chloride, oxycodone hydrochloride, penicillin, pentoxifylline, potassium chloride, pseudoephedrine hydrochloride, rabeprazole sodium, ranitidine hydrochloride, salbutamol, terfenadine, theophylline, tramadol hydrochloride, trandolapril, venlafaxine hydrochloride, verapamil hydrochloride, and alternative or pharmaceutically acceptable salts thereof

46. A device according to claim 37 where said active ingredient is a pharmaceutical agent for veterinary use.

47. A device according to claim 37 where said active ingredient is an insecticide or fungicide.

48. A device according to claim 37 where said active ingredient is a biocide or disinfectant.

49. A process for the preparation of a device according to claim 37 by dry granulation process comprising:

(a) blending said active ingredient and a insoluble polymer and optionally with a diluent;

(b) optionally milling and sieving the resulting blend with a mesh size suitable for the specific application;

(c) mixing said blend with a soluble or insoluble lubricant and compressing the blend into tablet into an appropriate shape using a punch machine;

(d) coating said tablet with a impermeable coating containing an insoluble polymer or a mixture of an insoluble polymer and pore-forming elements using a core-coating machine.

50. A process for the preparation of a chemical delivery device according to claim 37 by wet granulation process comprising:

(a) blending said biologically active ingredient and an insoluble polymer with water, an organic solvent or a mixture of water and an organic solvent and optionally with a diluent;

(b) drying the resulting blend at an appropriate temperature, milling and sieving the resulting blend with a mesh size suitable for the specific application;

(c) mixing said blend with a soluble or insoluble lubricant and compressing the blend into tablet into an appropriate shape using a punch machine;

(d) coating said tablet with a coating containing an insoluble polymer or a mixture of an insoluble polymer and pore-forming elements using a compression-coating machine.

51. A method of delivering a an active ingredient with a constant controlled release of an active compound into a fluid medium comprising:

(a.) incorporating at least one biologically active ingredient into a tablet having:

(*i*) a shaped core (*a*) having at least one planar release face wherein the area of the dissolution surface of said surface increases throughout the delivery period to compensate for an increase in the diffusion path length and (*b*) containing a compressed mixture of the biologically active ingredient homogeneously mixed with at least one insoluble polymer operable to release the biologically active ingredient from said exposed surface;

(*ii*) a coating surrounding and adhering to said core except the release face(s), said coating comprising an insoluble polymer or a mixture of an insoluble polymer and pore-forming elements operable to create channels in said impermeable coating to permit disintegration of the coating after release of said active ingredient is completed said coating disintegrating over a substantially longer period of time than is required for said

dissolution regulator to release said biologically active ingredient; and,

(b) placing said tablet in a fluid medium in need of the presence of said active ingredient.

52. A dissolution-controlled chemical delivery device providing substantially constant controlled-release of at least one active ingredient into a fluid medium throughout a substantial portion of the delivery period which composition comprises:

(*i*) a shaped core (*a*) having at least one planar release face wherein the dimensions of said face remain constant throughout a substantial portion of the delivery period, and (*b*) comprising a compressed mixture containing less than 90% (w/w) of the active ingredient homogeneously mixed with at least one dissolution regulator operable to release the active ingredient from said release face, and

(*ii*) a coating surrounding and adhering to said core except the release face(s) said coating disintegrating over a substantially longer period of time than is required for said dissolution regulator to release said biologically active ingredient.

53. A device according to claim 52 wherein said device is rectangular and said planar release surface is a square.

54. A device according to claim 52 wherein said core is a cylinder and said planar release face is a circle.

55. A device according to claim 52 wherein said core is a prism and said planar release surface is a polygon

56. A device according to claim 52 wherein said core has two exposed planar release surfaces.

57. A device according to claim 52 wherein the polymer coating is selected from a group consisting of ethyl cellulose, cellulose acetate, cellulose acetate butyrate

and cellulose acetate phthalate, polyvinyl alcohol, polyvinyl acetate and methacrylic acid copolymers.

58. A device according to claim 52 wherein said dissolution regulator is selected from a group consisting of hydroxypropyl cellulose, hydroxyethyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, methyl cellulose, soluble modified starches, gelatin, and acacia;

59. A device according to claim 52 where the active ingredient is a pharmaceutical agent for human use.

60. A device according to claim 59 where said active ingredient is selected from a group consisting of psychotherapeutic agents, anti-diabetic drugs, anticonvulsants, cardiovascular drugs, stroke treatment agents, respiratory therapies, anti-infective agents, migraine therapies, urinary tract agents, contraceptives, analgesics, cholesterol reducers, anti-arthritic agents, gastrointestinal products, muscle-relaxants, muscle-contractants, anti-Parkinson agents, anti-inflammatory agents, hormonal agents, diuretics, electrolytes, serotonin agonists and antagonists H2-antagonists muscle relaxants.

61. A device according to claim 59 where said active ingredient is selected from a group consisting of aspirin, bupropion hydrochloride, buspirone hydrochloride, carbamazepine, carbidopa, cephalosporin, cimetidine hydrochloride, citalopram hydrobromide, clarithromycin, clonidine, diclofenac sodium, diltiazem hydrochloride, dipyridamole, divalproex sodium, doxazosin mesylate, enalapril maleate, ethinyl estradiol, etodolac, fexofenadine hydrochloride, glipizide, haloperidol, ibuprofen, indomethacin, isosorbide dinitrate, isradipine, ketoprofen, labetalol, lansoprazole, levodopa, lithium carbonate, loratidine, lovastatin, methascopolomine chloride, metformin hydrochloride, metronidazole, methylphenidate hydrochloride, metoprolol succinate, morphine sulfate, naproxen sodium, nifedipine, nisoldipine, norethindrone acetate, omeprazole, oxybutynin chloride, oxycodone hydrochloride, penicillin, pentoxifylline, potassium chloride, pseudoephedrine hydrochloride, rabeprazole sodium, ranitidine hydrochloride, salbutamol, terfenadine, theophylline, tramadol hydrochloride, trandolapril,

venlafaxine hydrochloride, verapamil hydrochloride and alternative or pharmaceutically acceptable salts thereof. .

62. A device according to claim 52 where the active ingredient is a pharmaceutical agent for veterinary use.

63. A process for the preparation of a chemical delivery device according to claim 52 by wet granulation process comprising:

(a) blending said biologically active ingredient and a slow dissolving polymer with water, an organic solvent or a mixture of water and an organic solvent and optionally with a diluent;

(b) drying the resulting blend at an appropriate temperature, milling and sieving the resulting blend with a mesh size suitable for the specific application;

(c) mixing said blend with a soluble or insoluble lubricant and compressing the blend into tablet into an appropriate shape using a punch machine;

(d) coating said tablet with a polymer.

64. A method of delivering a substantially constant controlled release of an active compound into a fluid medium comprising:

(a.) incorporating at least one biologically active ingredient into a tablet having:

(*i*) a shaped core (*a*) having at least one planar release face wherein the dimensions of said face remain constant throughout a substantial portion of the delivery period, and (*b*) containing a compressed mixture containing less than 90% (w/w) of the biologically active ingredient homogeneously mixed with at least one dissolution regulator operable to release the biologically active ingredient from said release face,

(*ii*) a coating surrounding and adhering to said core except the release face(s), said coating disintegrating over a substantially

longer period of time than is required for said dissolution regulator to release said biologically active ingredient; and,

(b) placing said tablet in a fluid medium in need of the presence of said active ingredient.